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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/844,450 | 04/27/2001 | William H. Frey II | 83935 | 9084 |

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EXAMINER

YOUNG, JOSEPHINE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1623

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,450

Applicant(s)

FREY ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 45-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>6</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-44, in Paper No. 5, transmitted via facsimile on November 25, 2002, is acknowledged.

Accordingly, claims 45-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election without traverse of Species E, comprising methods of protecting a tissue comprising administering a phosphorylated compound comprising one or more of a group not categorized as a glycerol, amino acid, nucleoside or inositol, such as a hydrogen, a small alkyl group or an arachidonyl, in Paper No. 5, transmitted via facsimile on November 25, 2002, is acknowledged.

Election/Restrictions

Further restriction to one of the following inventions is now required under 35 U.S.C. 121:

- I. Claims 1-3, 4 and 32-44, drawn to methods of protecting tissue from oxidative stress, such as from free radicals, including heme/hydrogen peroxide and low molecular weight (LMW) inhibitor found in patients with Alzheimer's disease (AD), using a pyrophosphate analog, classified in class 514, subclass 75⁺, 102⁺.

- II. Claims 1-3, 12-15, 20-21 and 32-44, drawn to methods of protecting tissue or a subject from at least one carcinogenic or toxic metal, reducing poisoning of a subject by at least one metal, or reducing toxic actions of metal ions, using a pyrophosphate analog, classified in class 514, subclass 75⁺, 102⁺.
- III. Claims 5-11, 22-31 and 32-44, drawn to methods of increasing the efficacy of an agent that directly or indirectly affects a receptor, protecting a pharmacological agent in a formulation or increasing the efficacy of a neurological agent, using a pyrophosphate analog with said agent, classified in class 514, subclass 75⁺, 102⁺.
- IV. Claims 1-3, 16-19 and 32-44, drawn to methods of protecting tissue from or treating bacterial, fungal, algo or algae infection, using a pyrophosphate analog, classified in class 514, subclass 75⁺, 102⁺.
- V. Claims 1-3 and 32-44, drawn to drawn to methods of protecting tissue from something other than oxidative stress, toxic actions of at least one metal/metal ion, or bacterial, fungal, algo or algae infection, using a pyrophosphate analog, classified in class 514, subclass 75⁺, 102⁺.

Claims 1-3 link Groups I-II and IV-V and will be examined together with the Group that is elected as it pertains to the elected invention. Claims 32-44 link Group I-V and will be examined together with the Group that is elected as it pertains to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to patentably distinct methods with different functions and different effects. The function of the methods of Group I is to protect tissue from oxidative stress, such as from free radicals, including heme/hydrogen peroxide and low molecular weight (LMW) inhibitor found in patients with Alzheimer's disease (AD). The function of the methods of Group II is to protect tissue or a subject from at least one carcinogenic or toxic metal, to reduce poisoning of a subject by at least one metal, or to reduce toxic actions of metal ions. The function of the methods of Group III is to increase the efficacy of an agent that directly or indirectly affects a receptor, to protect a pharmacological agent in a formulation or to increase the efficacy of a neurological agent. The function of the methods of Group IV is to protect tissue from or to treat bacterial, fungal, algo or algae infection. The function of the methods of Group V is to protect tissue from something other than oxidative stress, toxic actions of at least one metal/metal ion, or bacterial, fungal, algo or algae infection.

The effect of Group I is tissue protected from oxidative stress. The effect of Group II is tissue or a subject protected from a carcinogenic or toxic metal/metal ion. The effect of the methods of Group III is the improved efficacy of a pharmacological agent. The effect of the methods of Group IV is the treatment of a bacterial, fungal, algo or algae infection. The effect of Group V is tissue protected from some other patentably distinct agent.

Therefore, the methods of one do not render obvious the methods of another.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A reference for one group could not reasonably be expected to be a reference for another. Further, searching all of the inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. To search the five independent and distinct inventions, set forth supra, would indeed impose an undue burden upon the examiner in charge of this application.

A telephone call was made to Applicant's Representative, Peter Forrest, on March 3, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

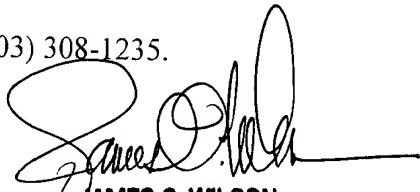
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
March 5, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600